

Effective Date: 9/2018
Revised: 12/2019
Reviewed: 9/2018, 12/2019, 4/2020, 1/2021, 1/2022, 2/2023
Pharmacy Scope: Medicaid
Medical Scope: Medicaid, Commercial, Medicare-Medicaid Plan (MMP)

SUBLOCADE (buprenorphine extended-release) INJECTION

POLICY

I. CRITERIA FOR INITIAL APPROVAL

Moderate to severe opioid use disorder

Authorization of 6 months may be granted for treatment of moderate to severe opioid use disorder in members 18 years of age or older when all of the following criteria are met:

- A. Member has initiated therapy with transmucosal buprenorphine containing product (delivering the equivalent of 8-24mg of buprenorphine daily) over a minimum of a 7 day period and is stable with clinically controlled cravings and withdrawal symptoms.
- B. Member is part of a complete treatment program that includes counseling and psychosocial support.
- C. Member is not receiving other opioids during therapy with Sublocade.
- D. Rationale is provided to support the member's inability to continue to use oral formulations of buprenorphine.
- E. The dose of Sublocade does not exceed 300mg a month.

II. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for treatment of moderate to severe opioid use disorder in patients when all of the following criteria are met:

- A. Member continues to meet the initial criteria in section I.
- B. Member is tolerating treatment.
- C. Member has documentation of a decrease in signs of opioid dependence relapse.

Pharmacy Dosing

Indication	Dose
Opiate use disorder	300 mg monthly for the first two months followed by a maintenance dose of 100 mg monthly.

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Medical Dosing

Indication	Dose	Maximum dose (1 billable unit = 100 mg)
Opiate use disorder	300 mg monthly for the first two months followed by a maintenance dose of 100 mg monthly.	3 units for the first two months, followed by a maintenance dose of 1 unit monthly

The following HCPCS/CPT codes are:

HCPCS/CPT Code	Description
Q9991	Injection, buprenorphine extended-release (Sublocade), less than or equal to 100 mg
Q9992	Injection, buprenorphine extended-release (Sublocade), greater than 100 mg

References:

1. Sublocade [prescribing information]. Indivior Inc. North Chesterfield, VA; August, 2022.
2. Comer S, Cunningham C, Fishman M, et al. ASAM National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use. American Society of Addiction Medicine, Copyright 2015. Available at: <https://www.asam.org/resources/guidelines-and-consensus-documents/npg>. Accessed on 1/24/2018.
1. ClinicalTrials.gov. U.S. National Institutes of Health. Available at: <https://clinicaltrials.gov/>. Accessed on 1/24/2018.
2. U.S. Food and Drug Administration. U.S. Department of Health and Human Services. Available at: <http://www.fda.gov/>. Accessed on 1/24/2018.
3. AMCP eDossier System. Dymaxium Healthcare Innovations, Ltd. Available at: <https://amcp.edossiers.com/>. Accessed on 1/24/2018.